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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,825	11/26/2003	Bernd Duesterberg	SCH-1994	4786
23599	7590	09/19/2006		
MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201			EXAMINER HANDY, NIKKI R	
			ART UNIT 1616	PAPER NUMBER

DATE MAILED: 09/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/721,825

Applicant(s)

DUESTERBERG ET AL.

Examiner

Nikki Handy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

SHELLEY A. DODSON
PRIMARY EXAMINER

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5/20/2005.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-25 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-84 of copending Application No. 11027690. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim a pharmaceutical kit with the same dosage of estrogen and progestin therefore one application would be obvious over the other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 17-20 are being rejected under 35 U.S.C. 101. The claimed invention in Claims 17-20 are directed to non-statutory subject matter. Therefore applicant is advised to amend the claims to read "a method of use" or "a method of using."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-19 and Claims 21-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Van Beek et al (Patent Application Publication No. U.S. 2002/0193356A1).

Van Beek et al. teach a kit containing a plurality of daily hormone units for use in a contraceptive method which consists of two alternating consecutive phases-an estrogenic and a progestogenic phase, sometimes referred to as a sequential method or sequential regimen. (See page 1, paragraph 1). Van Beek incorporates by reference, EP-A 0 628 312, which describes a method comprising one or more phases wherein one phase uses a combination of biogenic estrogen, synthetic estrogen and a progestogen and the other phases uses a placebo. An example given of a regimen which consists of 2 phases, one phase of 21 days using the combination of biogenic estrogen, synthetic estrogen and progestogen. (See page 1, paragraph 2). Van Beek further teaches a second hormonal component composed of a plurality of daily hormone units providing the daily units of the first hormonal component in a plurality which is

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lower than the plurality of daily units of the second hormonal component. (See page 1, paragraph 4). According to Van Beek best results are obtained with the kit in reference to the invention when the synthetic estrogen is ethinyl estradiol. (See page 5, paragraph 40). One embodiment that Van Beek teaches in the invention is concern with the kit containing a plurality of daily hormone units that contains estrogen in an amount equivalent to 5-15 micrograms of ethinyl estradiol. (See page 4, paragraph 31). The progestogen contained in the invention of Van Beek is selected from the group consisting of levonorgestrel and other progestins as recited in Claims 11 and 12. As stated by Van Beek the most preferable amount of progestogen in the daily unit is equivalent to 75-150 micrograms levonorgestrel. (See page 4, paragraph 34). In reference to the instant claims 14-16 of applicant, Van Beek teaches verbatim the method of administration and how often the pharmaceutical preparation should be given. (See page 3, paragraphs 25 and 26). Also in the instant claim 17, the method comprising administering is to a mammal, in particular a human wherein Van Beek the method is administered specifically to a female. (See page 1, paragraph 1). Van Beek describes a 21 day interval of hormone administration as opposed to the extended time referred to in the instant claims. Van Beek further describes the present method which offers the advantage that estrogen withdrawal symptoms do not occur. (See page 2, paragraph 12). The hormone units described by Van Beek are preferably for oral administration and arranged in a fixed sequence corresponding to the intended order of administration. The kits consist of 13-15 daily units and the packaging may be a tube or

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box or a strip. (See page 5, paragraph 42). Van Beek discloses each and every aspect the invention as claimed by applicant in the instant case.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Claim 20 is rejected under 35 U.S.C. 103(a) as being obvious over Van Beek in view of Casper et al. (US Patent No. 5,585,370).

Van Beek et al. teaches a kit containing a plurality of daily hormone units for use in a contraceptive method which consists of two alternating consecutive phases-an estrogenic and a progestogenic phase, sometimes referred to as a sequential method or sequential regimen. (See page 1, paragraph 1).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

However Casper et al. teaches in the invention a contraceptive formulation and a method of contraception which employs a combination of estrogen and progestin and wherein a short period of relatively dominant estrogenic activity alternates with a short period of relatively dominant progestagenic activity. (See page 1, lines 10-15). Casper further teaches a reduction in progestin dose that with the subject contraceptive

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formulation that is good for the management of acne. (See page 7, lines 43-46). The instant specification teaches a hormonal treatment that can be directed to avoid all derived symptoms of acne.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

It would have been obvious to include the specific mode of preventing acne of Casper into the administration of hormonal units given by Van Beek in view of the teachings of both references that these are known compounds in the kit for the use of contraceptive methods. As well as the teaching of Casper that said hormonal treatment will also avoid the derived symptoms of acne.

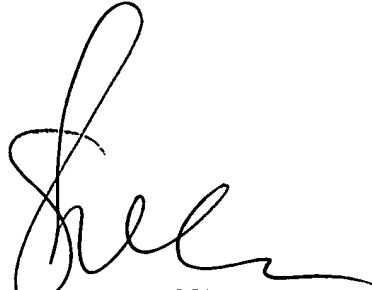
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikki Handy whose telephone number is (571) 272-9923. The examiner can normally be reached on Monday-Friday 8:30 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nikki Handy
Patent Examiner
Art Unit 1616



SHELLEY A. DODSON
PRIMARY EXAMINER